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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference Bisph₁01	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IN 2004/000238	International filing date (<i>day/month/year</i>) 10 August 2004 (10.08.2004)	Priority Date (<i>day/month/year</i>) 21 August 2003 (21.08.2003)
International Patent Classification (IPC) or national classification and IPC IPC⁷: C07F 9/38		
Applicant SUN PHARMACEUTICAL INDUSTRIES LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examination Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- | | | |
|-------|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| I. | <input checked="" type="checkbox"/> | Basis of the opinion |
| II. | <input type="checkbox"/> | Priority |
| III. | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV. | <input type="checkbox"/> | Lack of unity of invention |
| V. | <input checked="" type="checkbox"/> | Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI. | <input type="checkbox"/> | Certain documents cited |
| VII. | <input type="checkbox"/> | Certain defects in the international application |
| VIII. | <input type="checkbox"/> | Certain observations on the international application |

Date of submission of the demand 25.02.2005	Date of completion of this report 21 November 2005 (21.11.2005)
Name and mailing address of the IPEA/AT Austrian Patent Office Dresdner Straße 87 A-1200 Vienna Facsimile No. 1/53424/200	Authorized officer SLABY S. Telephone No. 1/53424/348

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IN 2004/000238

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____.

☐ the claims:

pages _____, as originally filed

pages _____, as amended (together with any statement) under Article 19

pages _____, filed with the demand

pages _____, filed with the letter of _____.

☐ the drawings:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____.

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____.

☐ the claims, Nos. _____.

☐ the drawings, sheets/fig _____.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as „originally filed“ and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/IN 2004/000238

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement	Novelty (N)	Claims 1-9	YES
		Claims ----	NO
	Inventive step (IS)	Claims 1-9	YES
		Claims ----	NO
	Industrial applicability (IA)	Claims 1-9	YES
		Claims ----	NO

Citations and explanations (Rule 70.7)

All documents cited in the search report are referred to in this communication.

In the light of the disclosure and the (combined) teachings of these documents, the present application is considered to meet the requirements, novelty and inventive step, since:

- a process for the preparation of biphosphonic acid compounds which comprises the reaction of a carboxylic acid with phosphorous acid and a phosphorous chloride wherein sulfolane is used as the solvent, is not known from prior art literature and
- there could not be derived any suggestion from the (combined) teachings of prior art that by the use of a water miscible and neutral solvent (sulfolane) instead of prior art solvents which are not water miscible (organic) solvents and/or not neutral solvents superior yields of biphosphonic acid compounds can be obtained and the reaction mixture can be conveniently worked up by quenching into water.

Industrial applicability is given.